



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of: **Nobushige DOISAKI et al.**

Art Unit: **1655**

Application Number: **10/535,413**

Examiner: **Randall O. Winston**

Filed: **November 17, 2005**

Confirmation Number: **5903**

For: **COMPOSITION CONTAINING ORGANIC SUBSTANCE HAVING DOUBLE  
BOND WITH IMPROVED OXIDATIVE STABILITY**

Attorney Docket Number: **052572**

Customer Number: **38834**

**SUBMISSION OF REPLY BRIEF**

Mail Stop: **Appeal Brief – Patents**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

January 22, 2009

Sir:

In reply to the Examiner's Answer dated December 11, 2008, a Reply Brief is submitted with this paper. This paper is being timely filed.

If any additional fees are due in connection with this submission, please charge our Deposit Account No. 50-2866.

Respectfully submitted,

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE BOARD OF PATENT APPEALS**  
**AND INTERFERENCES**

**REPLY BRIEF FOR THE APPELLANT**

Ex parte Nobushige DOISAKI et al. (Appellant)

**COMPOSITION CONTAINING ORGANIC SUBSTANCE HAVING**  
**DOUBLE BOND WITH IMPROVED OXIDATIVE STABILITY**

Serial Number: 10/535,413

Filed: November 17, 2005

Appeal No.:

Group Art Unit: 1655

Examiner: **Randall O. Winston**

Submitted by:

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Date: January 22, 2009

Appellants reply to the Examiner's Answer mailed on December 11, 2008. This paper is being timely filed.

### **ARGUMENT**

#### **(1) Examiner's Allegation Ignores Common Sense Of Person Of Ordinary Skill In The Art.**

Responding to Appellant's argument that the prima facie case of obviousness has been effectively rebutted by factual evidence demonstrating the synergistic effect of combining each claimed active ingredient, the Examiner alleged as follows:

The examiner disagrees with the appellant's argument because **the amounts of each active ingredient which demonstrate the unexpected synergism (as shown in Figures 1, 5, and 14), are not present in the claims. The synergistic amounts shown in Figures 1, 5, and 14 only vary from 1-2% of the sesame component and 0.01%-0.5% ascorbyl palmitate. The claims are not limited to any particular amounts of active ingredients and thus the claims encompass non-synergistic amounts of the active ingredients.** In order for the appellant's argument of synergism to be persuasive to overcome the prima facie case of obviousness as set forth above, the claimed composition needs to claim the amounts of the active ingredients sufficient to obtain the unexpected results due to synergism. Therefore, since the claimed composition is not limited to the active ingredients being present in amounts shown to be synergistic and thus demonstrate unexpected results, the assertion of unexpected results does not overcome the prima facie case of obviousness as set forth in the rejection above. . . . .

(Examiner's Statement, page 7, line 11 to page 8, line 4, emphasis added).

However, the Examiner's allegation ignores a common sense of a person of ordinary skill in the art. Once the synergistic results by the combination of the sesame component and ascorbic fatty acid or its ester are shown with respect to 1-2% of the sesame component and 0.01%-0.5%

ascorbyl palmitate, a person of ordinary skill in the art would reasonably expect similar synergistic result with respect to other amounts of the same combination. It would be a matter of degree. If the amount of sesame component and ascorbic acid component is less than the amounts shown in the present application, then a person having ordinary skill in the art would expect that the effect would be less than shown in the example according to the amount. On the other hand, if the amounts of sesame component and ascorbic acid component are more than the amounts shown in the examples in the present application, then a person having ordinary skill in the art would expect that the effect could be more which is correlative to the amount. Even if the effect of sesame component and ascorbic acid component might saturate at a certain level, it does not mean that there is no synergistic result of the present invention. Thus, to a person having ordinary skill in the art, it is sufficiently reasonable to conclude that the synergistic effects exists regardless of the amount of the sesame component and ascorbic fatty acid or its ester.

(2) Examiner's Reliance On Tallarida Is Erroneous.

Regarding the relationship between the unexpected results and the amounts of the active ingredients, the Examiner alleged that, even if there may be some other concentrations or ranges of concentrations that are synergistic and thus have unexpected results, it is not agreed that all concentrations of active ingredients encompassed by the claimed compositions would be synergistic. To support the allegation, the Examiner alleged as follows:

For example, Ronald J. Tallarida in his book named "Drug Synergism and Dose-Effect Data Analysis" on pages 8-10 provides a statistical analysis of an isobologram for the hypnotic effect of a combination of ethyl alcohol and chloral hydrate. In his figures, Tallarida discloses an isobologram showing line of additive and curves for combinations that are synergistic and sub-additive. **Tallarida states that the figures show that some of the data points appear to be well off the line of additivity, while others are**

**close to the line and have error bars that intersect it.** Therefore, Tallarida concludes that some combinations are synergistic whereas others are simply additive. Tallarida implies that synergism is not only a property of the drug pair but also depends on the relative amounts in the combination tested. This reference shows the general principle that unexpected synergism between components of a composition is present in only a range of proportions of the components in an unpredictable fashion.

(Examiner's Statement, page 8, line 14 to page 9, line 9). However, the Examiner's reliance on Tallarida is not appropriate.

Tallarida is a textbook about effects of drug on biological objects as is clear from the title "Drug Synergism and Dose-Effect Data Analysis." It is well known that, dose dependency of effect of drug is limited to a certain range, and the dose dependency is not found outside of the range. The effect of drugs on biological objects show sigmoid curves. In the case of drugs having this tendency, it is natural that synergistic effect changes depending on the concentration.

On the other hand, the present invention belongs to physical chemistry, which has nothing to do with the effects on biological objects. An antioxidant agent is a substance more susceptible to oxidation than the object substance. When such a antioxidant agent is added in an object substance, the antioxidant agent is oxidized before the object substance is oxidized. Therefore, if the more antioxidant agent is added, the more antioxidant effect is simply obtained. Therefore, sigmoid-curve effect of drugs on biological objects has nothing to do with the synergistic effect of the present invention. The synergistic effect of the present invention is further explained below.

### (3) Combination Of Sesamol And Ascorbyl Palmitate Makes Synergistic Effect.

Fig. 1 of the present application shows the absorbed oxygen in two days after storage at 60°C by fish oil containing 0.5 wt%  $\delta$ -tocopherol. The addition of sesamol alone or ascorbyl

palmitate alone does not significantly prevent the absorption of oxygen. The addition of ascorbyl palmitate alone rather increases the absorbed oxygen. Thus, addition of sesamol alone or ascorbyl palmitate alone have no significant effect. However, the addition of the combination of sesamol and ascorbyl palmitate dramatically decreases the absorption of oxygen. This is undoubtedly unexpected synergistic result.

(4) Amount Is Not Factor Of Synergistic Effect.

Figs. 10 and 11 of the present application shows that ascorbyl palmitate decreases first, and that the highly unsaturated fatty acid begins to be oxidized when ascorbyl palmitate disappears. It is regardless of the amount of sesamol because Fig. 10 is for addition of 0.5% sesamol and 0.1% ascorbyl palmitate, and Fig. 11 is for addition of 1.0% sesamol and 0.1% ascorbyl palmitate. Fig. 12 shows that when 0.1% ascorbyl palmitate was added four days later to the same system shown in Fig. 11, the antioxidant effect continued regardless of the amount of sesamol.

Thus, where sesamol and ascorbyl palmitate coexist, it is ascorbyl palmitate which is consumed first as an antioxidant. When ascorbyl palmitate is consumed, highly unsaturated fatty acid begins to be oxidized even though sesamol remains. Despite the fact that addition of ascorbyl palmitate alone has no antioxidant effect and rather increases the absorbed oxygen as mentioned above, ascorbyl palmitate works as an antioxidant under coexistence of sesamol. This is a remarkable synergistic effect, which was not expected.

It is found that the antioxidant effect continues while ascorbyl palmitate remains from the fact that the antioxidant effect continues when ascorbyl palmitate is additionally supplied. The data shown in Fig. 12 indicates that, under coexistence of sesamol, where the more ascorbyl

palmitate is added, the longer the antioxidant effect will continue. This indicates that the amount of ascorbyl palmitate to be added can be determined according the time period of storage.

Thus, synergistic the antioxidant effect does not depend on a particular amount or ratio between sesamol and ascorbyl palmitate.

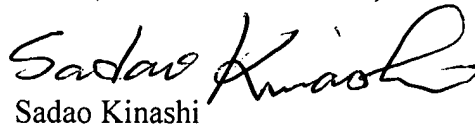
### **CONCLUSION**

As discussed above, the Examiner's finding that Claims 1-3 and 5-20 are obvious under 35 USC 103(a) over Kataoka et al. and/or Granata in view of Chavali et al., Maguire et al., Chen et al. and Wechter ignores a common sense of a person having ordinary skill in the art. The Honorable Board is respectfully requested to reverse the rejection of the Examiner.

If this paper is not timely filed, Appellant hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 50-2866, along with any other additional fees that may be required with respect to this paper.

Respectfully submitted,

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